

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

**ASTRAZENECA AB, ASTRAZENECA :
LP, KBI-E, INC., and POZEN INC., :**

Civil Action No. 11-2317 (JAP)

Plaintiffs,

V.

DR. REDDY'S LABORATORIES INC. :
And DR. REDDY'S LABORATORIES :
LTD., :

MEMORANDUM OPINION AND ORDER

and

**LUPIN LTD. and LUPIN
PHARMACEUTICALS INC.**

and

**ANCHEN PHARMACEUTICALS,
INC.**

Defendants.

This matter comes before the Court on Plaintiffs AstraZeneca AB, AstraZeneca LP, KBI-E, Inc. (collectively, “AstraZeneca”) and Pozen Inc.’s (“Pozen”) Motion for Leave to Amend Responses to Defendants’ Invalidity Contentions [dkt. no. 98]. Defendants Dr. Reddy’s Laboratories, Inc. and Dr. Reddy’s Laboratories Ltd. (collectively, “DRL”) filed Opposition [dkt. no. 116] and Plaintiffs have replied [dkt. no. 125]. The Court granted DRL leave to submit a Sur-Reply and DRL did so [dkt. no. 127]. The Court has considered all of the submissions of the Parties pursuant to FED. R. CIV. P. 78 and, for the reasons set forth below, Plaintiffs’ Motion is **DENIED.**

I. INTRODUCTION

This Hatch-Waxman case was commenced on April 21, 2011. Plaintiffs allege that Defendants infringed one Pozen patent (U.S. Patent 6,926,907—“the ‘907 patent”) and five AstraZeneca patents (not at issue in the instant Motion) by filing Abbreviated New Drug Application No. 202461 (“DRL’s ANDA”) with the U.S. Food and Drug Administration (“FDA”). See generally Pl.’s Complaint. DRL’s ANDA seeks approval to market a generic version of AstraZeneca’s VIMOVO® drug prior to the expiration of Plaintiffs’ patents. Id.

DRL is the first ANDA filer for any generic VIMOVO® product. Id. Lupin Ltd. and Lupin Pharmaceuticals, Inc. (“Lupin”) and Achen Pharmaceuticals, Inc. (“Achen”) separately filed later, discrete ANDAs for their own generic VIMOVO® products. Id. The Court has consolidated Plaintiffs’ cases against DRL, Lupin and Achen for discovery purposes only. See dkt. nos. 41 and 82.

A. The ‘907 Patent

Plaintiffs seek leave to amend their responses with regard to the ‘907 patent only. The ‘907 patent has 55 claims. On November 17, 2011, Plaintiffs served their Disclosure of Asserted Claims pursuant to L. Pat. R. 3.6(b). Plaintiffs asserted that DRL infringed 21 claims of the ‘907 patent (i.e., claims 1, 5, 9-17, 22, 23, 35, 48 and 50-55). In their November 23, 2012 Invalidity Contentions, DRL contended that each of the 21 asserted claims were invalid. DRL also addressed each of the remaining 34 claims of the ‘907 patent. In their January 17, 2012 Responses to DRL’s Invalidity Contentions, Plaintiffs responded to DRL’s contentions for six of the 21 asserted claims (i.e., claims 5, 15, and 52-55) of the ‘907 patent. Subsequently, Plaintiffs further narrowed their asserted claims of the ‘907 patent to claims 5, 15, 52, 53, and 54. DRL

thereafter informed Plaintiffs they would only contest the validity of the five claims that remained and withdrew their invalidity contentions as to the other claims. See Def.’s Opp. at 8.

As a result of DRL’s Opposition to the instant Motion, Plaintiffs introduced new “compromise” amended responses in their Reply. These new responses purport to address only claims 5, 15, 52, 53, and 54.¹

II. ARGUMENT

Plaintiffs advance two primary arguments in support of their Motion. First, Plaintiffs claim they should be granted leave to amend in order to correct an “oversight” by prior counsel. Pl.’s Br. at 3; Pl.’s Reply at 3-4. According to Plaintiffs, primary responsibility for litigating each of the six patents-in-suit was previously divided between two law firms, with prior counsel taking the lead on the ‘907 patent. Pl.’s Br. at 3. On July 26 and 27, 2012, prior counsel withdrew. At that time, Plaintiffs’ current counsel assumed primary responsibility for the ‘907 patent. Id. Plaintiffs now claim they should be granted leave in order to correct “omissions” and “oversights” by prior counsel in the previously submitted responses.² Id.; Pl.’s Reply at 3-4. DRL claims this argument is moot because it withdrew its invalidity contentions for all claims except those already contested and responded-to claims 5, 15, 52, 53 and 54. Def.’s Opp. at 8.

Plaintiffs also argue that they should be permitted to amend their responses to complete the “housekeeping” task of ensuring that their responses are “complete and in line with what has

¹ DRL nonetheless claims that Plaintiffs’ compromise contentions still assert validity arguments for non-asserted claims 1, 9-17, 22, 23, 35, 48, 50, 51, and 55. Def.’s Sur-Reply at 4 (citing Plaintiffs’ Reply Redline, dkt. no. 125-2, at Stout Decl., Ex. A). Because Plaintiffs’ Motion is denied, this issue is moot.

² Plaintiffs original Memo argued that leave should be granted to correct inadvertent omissions with regard to the 15 claims for which invalidity was asserted by DRL, but not addressed by Plaintiffs’ original response. Pl.’s Br. at 5. These 15 claims were later conceded by Plaintiffs. See Pl.’s Reply at 1. This argument was, in turn, adapted to support Plaintiffs’ position that they should be permitted leave to amend with regard to the five contested claims.

already been filed in the consolidated litigations.” Pl.’s Br. at 4. For reasons more fully outlined below, DRL vehemently contests this justification. See Def.’s Opp. at 8-11.

III. DISCUSSION

A. Legal Standard

The Local Patent Rules “exist to further the goal of full, timely discovery and provide all parties with adequate notice and information with which to litigate their cases.” Computer Accelerations Corp. v. Microsoft Corp., 503 F.Supp.2d 819, 822 (E.D.Tex. 2007). The rules are designed specifically to “require parties to crystallize their theories of the case early in litigation and to adhere to those theories once they have been disclosed.” Atmel Corp. v. Info. Storage Devices, Inc., 1998 WL 775115, at *2 (N.D. Cal. Nov. 5, 1998). This is “to ‘prevent the ‘shifting sands’ approach to claim construction.” O2 Micro Int’l Ltd. v. Monolithic Power Sys., Inc., 467 F.3d 1355, 1364 (Fed. Cir. 2006) (citing Atmel, 1998 WL 775115, at *2). As distinguished from the liberal standard for amending pleadings, “the philosophy behind amending claim charts is decidedly conservative.” Atmel, 1998 WL 775115, at *2. However, Rule 3.7 “is not a straitjacket into which litigants are locked from the moment their contentions are served”; instead, “a modest degree of flexibility [exists], at least near the outset.” Comcast Cable Communs. Corp. v. Finisar Corp., 2007 WL716131, at *2 (N.D. Cal. March 2, 2007). Therefore, while “preliminary infringement contentions are still preliminary” it is important to recognize that the Local Patent Rules strive to have the parties establish their contentions early on. General Atomics v. Axis-Shield ASA, 2006 WL 2329464, at *2 (N.D.Cal. Aug. 9, 2006).

Pursuant to L. Pat. R. 3.7, leave to amend responses to invalidity contentions may be granted “only by order of the Court upon a *timely* application and showing of *good cause*.”

(emphasis added). Rule 3.7 provides a nonexhaustive list of circumstances that may, absent undue prejudice to the adverse party, support a finding of good cause:

(a) a claim construction by the Court different from that proposed by the party seeking amendment; (b) recent discovery of material prior art despite earlier diligent search; (c) recent discovery of nonpublic information about the Accused Instrumentality which was not discovered, despite diligent efforts, before the service of the Infringement Contention; (d) disclosure of an infringement contention by a Hatch- Waxman Act party asserting infringement under L. Pat. R. 3.6(g) that requires response by the adverse party because it was not previously presented or reasonably anticipated; and (e) consent by the parties in interest to the amendment and a showing that it will not lead to an enlargement of time or impact other scheduled deadlines . . .

L. Pat. R. 3.7. Good cause “considers first whether the moving party was diligent in amending its contentions and then whether the non-moving party would suffer prejudice if the motion to amend were granted.” Acer, Inc. v. Tech. Prob. Ltd., 2010 WL 3618687, at *3 (N.D. Cal. Sept. 10, 2010) (citing O2 Micro, 467 F.3d 1355, 1355). Importantly, however, the Court may only consider prejudice to the non-moving party if the moving party is able to demonstrate diligence. Apple v. Samsung, 2012 U.S. Dist. LEXIS 83115, at *13 (N.D. Cal. Mar. 27, 2012) (collecting cases).

In determining whether good cause exists, courts have also considered such other factors as (1) the reason for the delay, including whether it was within the reasonable control of the party responsible for it; (2) the importance of what is to be excluded; (3) the danger of unfair prejudice; and (4) the availability of a continuance and the potential impact of a delay on judicial proceedings. See Oy Ajat, Ltd. v. Vatech Am., Inc., 2012 WL 1067900, at *20-21 (D.N.J. Mar. 29, 2012) (collecting cases); see also Computer Acceleration Corp. v. Microsoft Corp., 503 F. Supp. 2d 819, 822 (E.D. Tex. 2007) (collecting cases).

B. Diligence

Courts have understood diligence to require a “showing that the party seeking leave to amend acted . . . promptly [in] moving to amend when new evidence is revealed in discovery.” O2 Micro, 467 F. 3d 1355, 1363, 1366 (collecting cases). This requirement is consistent with L. Pat. Rule 3.7’s requirement that the Motion be “timely.” As with good cause in general, the burden “is on the movant to establish diligence rather than on the opposing party to establish lack of diligence.” O2 Micro, 467 F. 3d 1355, 1366. For the reasons discussed below, the Court finds that Plaintiffs were not diligent in moving to amend.³

1. Prior Counsel’s Withdrawal

Plaintiffs argue first that withdrawal of prior counsel provides good cause to amend. This argument is not persuasive. Plaintiffs submitted their original responses on January 17, 2012—nearly seven months before filing the instant Motion to Amend. Although Plaintiffs claim, and the Court does not dispute, that the ‘907 patent was previously handled by prior counsel, the January 17th responses were nonetheless served by the same firm which filed the instant Motion. And Plaintiffs’ ‘of counsel’ attorneys from three large, reputable firms also signed both the January 17th responses as well as the instant Motion. Thus, with the exception of prior counsel, the attorneys involved in Plaintiffs’ original responses and Plaintiffs’ current Motion to Amend are the same. Given the sophistication and number of attorneys involved, the Court is not persuaded that Plaintiffs were diligent in either discovering prior errors or omissions, or moving to amend their responses until seven months after they were first submitted.

³ Plaintiffs contend, *inter alia*, that their Motion should be granted because “DRL’s [Opposition] fails to demonstrate untimeliness or a lack of good cause.” Pl.’s Reply at 2. However, it is Plaintiffs—not DRL—who must carry this burden.

a. *Oversights & Omissions*

The Court would reach the same conclusion even if it accepted Plaintiffs' position that the proposed amendments are intended to correct oversights or genuine errors. Plaintiffs are correct in noting that this Court has granted leave to amend infringement contentions to correct inadvertent omissions. However, the case cited by Plaintiffs, TFH Publications, Inc. v. Daskocil Mfg. Co., Inc., 705 F. Supp. 2d 361 (D.N.J. 2010), is inapposite. In that case, plaintiff TFH moved to amend its infringement contentions within two months of filing their initial contentions. Id. at 363. Here, Plaintiffs waited seven months. The length and nature of Plaintiffs' proposed amendments, moreover, do not suggest inadvertent omission. To the contrary, they are more in line with changes that reflect a shift in theory or position by Plaintiffs. Still, even if the amendment were provoked by genuine errors or omission, Plaintiffs cite no case which allows for amendment after a similar period of time has passed.

The procedural posture in TFH was also significantly different. In noting that that case was still in its relatively early stages, this Court explained, "Local Patent Rule disclosures are in their infancy, discovery demands have not yet [been] exchanged, Markman briefing is months away and scheduling of the Markman hearing will not even be discussed [for another 4 months]." Id. at 366. In this case, conversely, disclosures have long been served, Markman briefing is complete, and a Markman hearing took place on December 19, 2012. Therefore, unlike TFH, this case is no longer in its early stages.

Finally, Plaintiffs' argument that the amendments are necessary to correct inadvertent errors or omissions would appear to be at odds with the amended responses' citations to recent

deposition discovery.⁴ After all, the original contentions were drafted nearly six months before Dr. Horn's deposition. For all of the reasons discussed above, Plaintiffs have failed to demonstrate, and the Court does not find any omission or error which would provide good cause to amend.

2. Consolidation

Plaintiffs next argue that they should be permitted to amend their Responses in order to bring them in line with the other two defendants, Lupin and Anchen, in these consolidated actions. This is not the purpose or function of consolidation. Instead, "consolidation is permitted as a matter of convenience and economy in administration, but does not merge the suits into a single cause, or change the rights of the parties, or make those who are parties in one suit parties in another." Johnson v. Manhattan Ry. Co., 289 U.S. 479, 496-97 (1933). As the Third Circuit has recognized, "Johnson remains the 'authoritative' statement on the law of consolidation." Cella v. Togum Constructeur Ensembleier en Industrie Alimentaire, 173 F.3d 909, 912 (3d Cir. 1999) (citation omitted). Here, the cases were consolidated for discovery purposes only. The law is well-settled on this issue and Plaintiffs cite no authority to advance their contrary proposition. Plaintiffs, therefore, may not amend their responses simply to promote uniformity among the consolidated actions.

C. Prejudice

In deciding whether Plaintiffs' proposed amendments would unfairly prejudice DRL, the Court considers whether permitting the proposed amendments would (1) require DRL to expend

⁴ In a footnote, Plaintiffs argue that they should be permitted to amend their Responses in order to disclose additional factual support for their validity positions in light of the deposition of Dr. John Horn, DRL and Lupin's shared expert. Pl.'s Reply at 2-3. This deposition took place on June 14, 2012. Id. at 2.

significant additional resources; or (2) significantly delay the resolution of the dispute. See TFH Publications, Inc. v. Daskocil Mfg. Co., Inc., 705 F. Supp. 2d 361, 366 (D.N.J. 2010). Because the Court finds that Plaintiffs were not diligent in moving to amend, it need not—and, indeed, should not—consider prejudice at all. See O2 Micro Int'l Ltd. v. Monolithic Power Sys., Inc., 467 F.3d 1355, 1368 (Fed. Cir. 2006). Nevertheless, several factors suggest prejudice to DRL.

First, the amended contentions consist of 15 pages of new material which DRL claims include “entirely new validity theories, a plethora of new references, as well as myriad citations to the June 14, 2012 deposition transcript of Dr. John R. Horn” Def.’s Opp. at 9; see also Def.’s Sur-Reply at 4-5. Plaintiffs do little to dispute this position other than note that such amendments would not require a response by DRL. Technically, Plaintiffs are correct that no such response is contemplated by the Local Rules. However, this point says nothing of the additional resources DRL would need to expend in order to defend against the new theories and defenses introduced by Plaintiffs; nor does it reassure DRL that its concerns are invalid or untrue.

Second, as noted above, this proceeding is no longer in its early stages. The Parties completed claim construction discovery and briefing on September 27, 2012 and a Markman hearing occurred on December 19, 2012. Because “the Local Patent Rules require parties to crystallize their theories of the case early in litigation and to adhere to those theories once they have been disclosed,” King Pharmaceuticals, Inc. v. Sandoz Inc., 2010 WL 2015258, at *4 (D.N.J. May 20, 2010), allowing amendment at this stage of the litigation would unfairly allow Plaintiffs to amend their previously disclosed theories of infringement.

IV. CONCLUSION & ORDER

The Court has considered the papers submitted pursuant to FED. R. CIV. P. 78 and, for the reasons set forth above,

IT IS on this 18th day of March, 2013,

ORDERED that Plaintiffs' Motion for leave to file Amended Responses to DRL's Invalidity Contentions is **DENIED**; and it is further

ORDERED that a telephone status conference, to be initiated by counsel for Plaintiffs, has been scheduled in this matter for **March 26, 2013** at **11:30 A.M.**

/s/ Douglas E. Arpert

DOUGLAS E. ARPERT

UNITED STATES MAGISTRATE JUDGE